DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Stryker Communications
% TUV Rheinland of North America, Inc.
Mr. Tamas Borsai
Program Manager
12 Commerce Road
Newton, CT 06470

Re: K100852
Trade/Device Name: Stryker SwitchPoint Infinity® 3 Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCS
Dated (Date on orig SE ltr): April 20, 2010
Received (Date on orig SE ltr): April 22, 2010

Dear Mr. Borsai,

This letter corrects our substantially equivalent letter of May 6, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

stryker®
Communications

510(k) Number (if known): K100852

Device Name: **Stryker SwitchPoint Infinity® 3 Control System**

Stryker SwitchPoint Infinity® 3 Control System is intended to be a central point of control and integration of ancillary compatible equipment, audio, video, and data routing, as well as teleconferencing for medical personnel.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100852

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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Stryker SwitchPoint Infinity® 3 Control System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Device Proprietary Name: Stryker SwitchPoint Infinity® 3 Control System

Device Common Name: Stryker SwitchPoint Infinity® 3 or SPI3

Classification Name: GCJ

Classification Number: 21CFR § 876.1500 – Accessory to Laparoscope, General and Plastic Surgery

Sponsor: Stryker Communications
1410 Lakeside Parkway # 100
Flower Mound, Texas 75028
Phone: 972-410-7279
Fax: 408-754-8356

Contact Person: Alma Relja, RAC

Date Prepared: March 9, 2010

This submission describes the Stryker SwitchPoint Infinity® 3 Control System intended for use as a central point of control and integration of ancillary compatible equipment, audio, video, and data routing, as well as and teleconferencing for medical personnel. The system provides a user interface through which to centrally control and provide visual status of various compatible devices including surgical devices, such as through the Stryker SIDNE™ system, as well as other devices, such as audio/video equipment used by medical personnel. It also functions as a matrix router capable of dynamically routing an array of audio, video, or other data sources to an array of audio, video or other data destinations. The routing capability is used to integrate local audio/video sources and destinations within a room. The SPI3 system provides an interface to facilitate audio/video communications to other rooms within the hospital campus, as well as off-site.

Equivalence for this device is based on similarities in intended uses, design and operational principles to the following substantially equivalent devices: Stryker SwitchPoint Infinity Control System (K033132), Olympus EndoALPHA Integrated Endosurgery System (K051613), and KSEA Storz Communication Bus (SCB) Media Control (K020640). The minor differences between the Stryker SwitchPoint Infinity® 3 Control System and the predicate device raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended use of the device. Therefore, based on the applicable testing and the equivalence information presented in this submission, Stryker Communications believes that the Stryker SwitchPoint Infinity® 3 Control System does not raise any new safety or efficacy issues.